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CORTEX

JAN 12 2011

510(k) Summary for Mixed Media Marker

Preparation date: January 04, 2011

Manufacturer: Cortex Manufacturing Inc.
421 South Davies Rd.
Lake Stevens WA 98258

Contact: Andrew Jones
Phone: (425) 334-2277

Trade Name: Mixed Media Marker
Product Code: NEU
Common Name: Implanted Marker
Classification: 878.4300
Class: II

SE Devices:

(K071614)	Trade name:	Implanted Fiducial	CIVCO Medical Solutions
(K100267)	Trade name:	FlexiMarc	Cortex Manufacturing Inc.

Device Description:

These implanted markers are used to identify the location of normal or diseased tissue for future treatments. The marker is placed at or near the treatment site and can be visualized in subsequent imaging studies. The location of the treatment area is then identified with respect to the marker.

The markers are fabricated of biocompatible materials. Specifically, gold (99.99%), medical grade titanium or PEEK Optima (polymer) with a medical grade stainless steel core.

They are available in varying lengths and have a diameter of 1.0 MM (+/- 0.2 MM)

They are intended for single use and are permanently implanted in the body. They are available pre-sterilized in accordance with FDA QSR sterilization procedures.

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Intended Use Statement with Additional Use Data

The Mixed Media Markers (MMM) are intended to be implanted into the body in situations where the location of specific anatomy, normal or diseased, needs to be marked for a future medical procedure. The MMM can be visualized using medical imaging devices; the MMM provides a reference from which the treatment can be guided. MMM's not intended for use with ultrasonography.

Technological Characteristics

These new markers vary only in material. The predicate devices are made of all gold or a combination of gold and other absorbable materials while the new markers are fabricated of gold and titanium or PEEK-Optima polymer and medical grade stainless steel. Sufficient testing has been performed to show that the change in materials did not adversely affect the safety or effectiveness of the new device.

Performance Comparison (Image Based)

These markers have been imaged using the typical medical imaging devices and they are visible in all of the modalities required.

Conclusion

The change in material composition did not adversely affect the safety or effectiveness of the new device. The new markers image in the same fashion as the predicate devices thus met the rules governing substantial equivalence.

CORTEX MANUFACTURING
421 SOUTH DAVIES RD.
LAKE STEVENS, WA 98258
(425) 334-2277

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621 SR 9 NE
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Cortex Manufacturing, Inc.
% Mr. Andrew Jones
421 South Davies Road
Lake Stevens, Washington 98258

JAN 12 2011

Re: K102506
Trade/Device Name: Mixed Media Marker (MMM)
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: NEU
Dated: December 14, 2010
Received: December 14, 2010

Dear Mr. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

JAN 12 2011

Indications for Use

510(k) Number: K102506

Device Name: Mixed Media Marker (MMM)

Indications For Use:

The Mixed Media Markers (MMM) are intended to be implanted into the body in situations where the location of specific anatomy, normal or diseased, needs to be marked for a future medical procedure. The MMM can be visualized using medical imaging devices; the MMM provides a reference from which the treatment can be guided. MMM's not intended for use with ultrasonography.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K102506